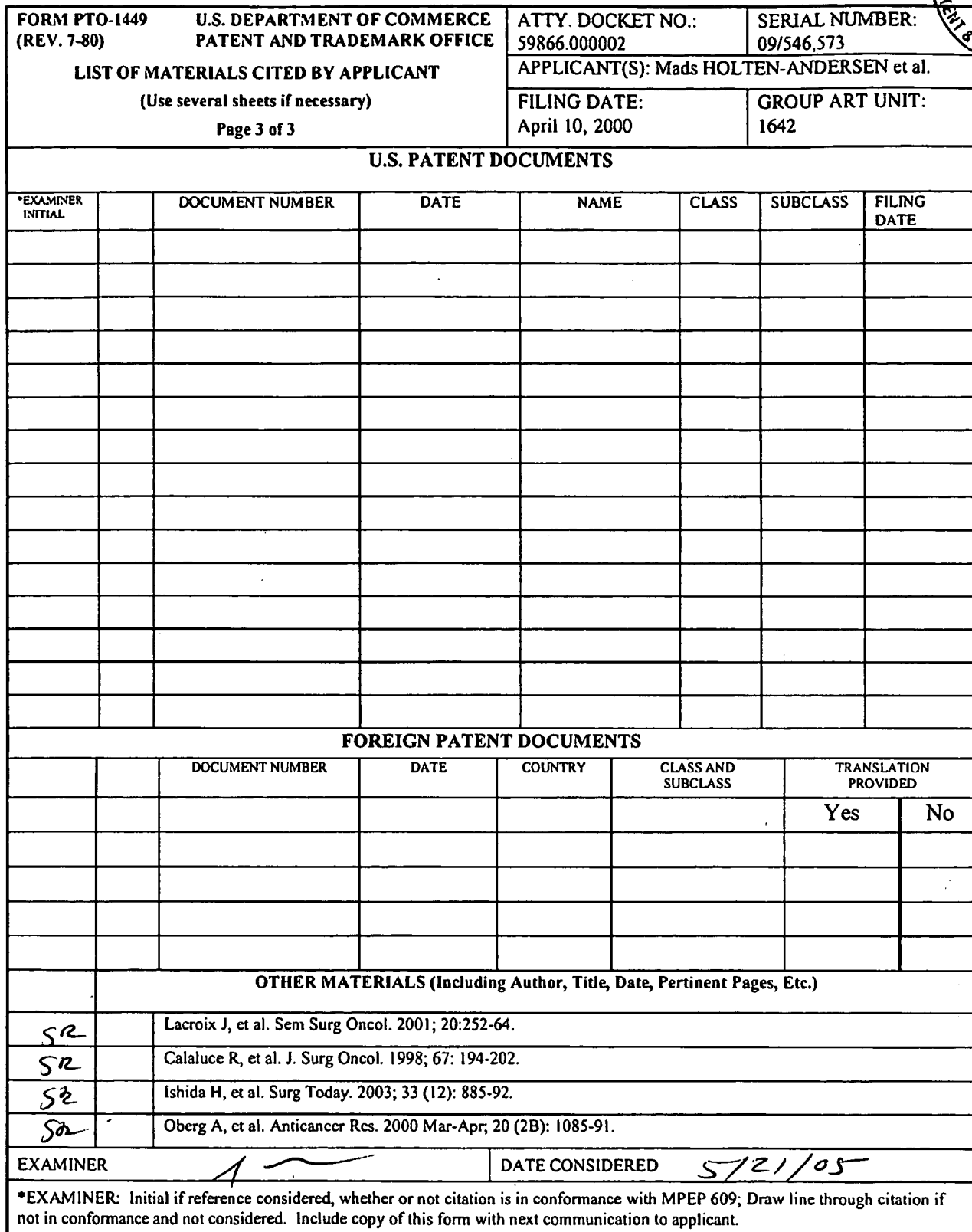


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FORM PTO-1449 (Modified)			Attorney Docket No.: 019829000310		Application No.: 09/546,573	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Applicant: Holten-Andersen, Mads et al.			
			Filing Date: April 10, 2000		Group: 1642	
Reference Designation			U.S. PATENT DOCUMENTS			Page 1
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
___ AA						
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FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
___ <u>SR</u> AM	PA 1999 00476	09 April 1999	Denmark	—	—	—
___ AN						
___ AO						
___ AP						
___ AQ						
___ AR						
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
___ <u>SR</u> AS	International Search Report for International Application No. PCT/DK 00/0170 dated 10 August 2000					
___ AT						
___ AU						
___ AV						
___ AW						
EXAMINER <u> A </u>		DATE CONSIDERED <u>5/21/05</u>				

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number	09/546,573
Filing Date	April 10, 2000
First Named Inventor	M. N. HOLTEN-ANDERSEN et al.,
Art Unit	1642
Examiner Name	S. L. Rawlings, Ph.D.
Attorney Docket Number	59866.000002

Sheet 1 of 1

FOREIGN PATENT DOCUMENTS

Examiner Initial	Cite No.	FOREIGN PATENT DOCUMENT		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	TRANSLATION	
		Country Code:	Number - Kind Code (if known)				YES	NO
SR	1.	WO	00/62070	10-19-2000	Holten-Andersen et al.		<input checked="" type="checkbox"/>	<input type="checkbox"/>

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION	
			YES	NO
SR	2.	HOLTEN-ANDERSEN, MADS N. et al., "Plasma levels of Tissue Inhibitor of Metalloproteinases 1 measured during follow-up of colorectal cancer patients have clinical value in predicting patient outcome," Proceedings Of The American Association For Cancer Research Annual, Vol. 43, March 2002, page 715 (Abstract)	X	
SR	3.	TAKADA, N. et al., "Postoperative sequential changes of serum levels of matrix metalloproteinase and tissue inhibitor of metalloproteinase in Japanese patients with the squamous cell carcinoma of esophagus," Proceedings Of The American Association For Cancer Research Annual, Vol. 40, March 1999, page 346 (Abstract)	X	
SR	4.	ZUCKER, STANLEY et al., "Plasma assay of gelatinase B: Tissue inhibitor of metalloproteinase complexes in cancer," Cancer (Philadelphia), Vol. 76, No. 4, 1995, pages 700-708	X	
SR	5.	HOLTEN-ANDERSEN, MADS N. et al., "Total levels of tissue inhibitor of metalloproteinases 1 in plasma yield high diagnostic sensitivity and specificity on patients with colon cancer," Clinical Cancer Research: An Official Journal Of The American Association For Cancer Research, Vol. 8, No. 1, January 2002, pp. 156-164	X	
SR	6.	ZHOU, W. et al., "Identifying markers for pancreatic cancer by gene expression analysis," Database Medline [Online], Abstract of Cancer Epidemiology, Biomarkers & Prevention: A Publication Of The American Association For Cancer Research, Cosponsored by The American Society Of Preventive Oncology, 2/1998, Vol. 7, No. 2, 2 pages, (Abstract)	X	
SR	7.	International Search Report for Application No. PCT/DK03/00230, mailed September 24, 2003	X	

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PTO/SB/08A (08-C0)

Approved for use through 10/31/2002. OMB 0651-0031
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Substitute for form 1449A/PTO <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(use as many sheets as necessary)</p>		Complete if Known <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>09/546,573</td> </tr> <tr> <td>Filing Date</td> <td>04-10-2000</td> </tr> <tr> <td>First Named Inventor</td> <td>Mads Holten-Andersen et al.</td> </tr> <tr> <td>Group Art Unit</td> <td>1642</td> </tr> <tr> <td>Examiner Name</td> <td>S. Rawlings</td> </tr> <tr> <td>Attorney Docket Number</td> <td>59866.000002</td> </tr> </table>		Application Number	09/546,573	Filing Date	04-10-2000	First Named Inventor	Mads Holten-Andersen et al.	Group Art Unit	1642	Examiner Name	S. Rawlings	Attorney Docket Number	59866.000002
Application Number	09/546,573														
Filing Date	04-10-2000														
First Named Inventor	Mads Holten-Andersen et al.														
Group Art Unit	1642														
Examiner Name	S. Rawlings														
Attorney Docket Number	59866.000002														
Sheet	1	of	1												

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
SR	U1	5,324,634		Zucker	06-28-1994	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₄
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
SR	F1		9738314	WO	Miller et al.	10-16-1997		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SR	P1	National Library of Medicine, PubMed Website, "Serum levels of a tissue inhibitor of metalloproteinases-1 (TIMP-1) in bladder cancer patients", Naruo S et al., Int J Urol, Vol. 1, No. 3 September 1994, pp. 238-231, see abstract	
	P2	National Library of Medicine, PubMed Website, "Tissue inhibitors of metalloproteinases (TIMP) in invasion and proliferation", Henriët P. et al., APMIS, Vol. 109, No. 1, January 1999, pp. 111-119, see abstract	
	P3	Patent Abstracts of Japan, JP8136548 A, Morinaga, 05-31-1996	
	P4	Dialog Information Services, File 159, Cancerlit, accession no. 93691448, Guillem JG et al., "Evaluation of tissue inhibitor of metalloproteinase-1 (TIMP-1) as a prognostic marker of human colorectal cancer invasion", Proc Annu Meet Am Assoc Cancer Res; 34:A466 1993	
	P5	Dialog Information Services, File 159, Cancerlit, accession no. 96647008, "Elevated tissue inhibitor of metalloproteinase 1 RNA in colorectal cancer stroma correlates with lymph node and distant metastases" Clin Cancer Res; 1(8): 899-906 1995 Zeng Z et al.	

Examiner Signature		Date Considered	5/21/05
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08A (10/01) (modified)
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number		09/546,573	
			Filing Date		April 10, 2000	
			First Named Inventor		Mads N. Holten-Andersen	
			Art Unit		1642	
			Examiner Name		S. Rawlings	
Sheet	1	of	1	Attorney Docket Number		59866.000002
NON-PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION			
			YES	NO		
SR	1.	Mads N. Holten-Andersen et al., "Measurement of the Noncomplexed Free Fraction of Tissue Inhibitor of Metalloproteinases I in Plasma by Immunoassay", <i>Clinical Chemistry</i> 48:8, 1305-1313 (2002)				
	2.	Mads N. Holten-Andersen et al., "Total Levels of Tissue Inhibitor of Metalloproteinases 1 in Plasma Yield High Diagnostic Sensitivity and Specificity in Patients with Colon Cancer", <i>Clinical Cancer Research</i> , Vol. 8, 156-164, January 2002				
EXAMINER SIGNATURE 			DATE CONSIDERED 5/21/05			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Substitute for form 1449A/PTO		
				Application Number		09/546,573
				Filing Date		April 10, 2000
				First Named Inventor		Mads N. Holten-Andersen
				Art Unit		1642
Examiner Name		S. Rawlings				
Sheet	1	of	1	Attorney Docket Number		59866.000002

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SR	1.	Mads N. Holten-Andersen et al., "Measurement of the Noncomplexed Free Fraction of Tissue Inhibitor of Metalloproteinases I in Plasma by Immunoassay", <i>Clinical Chemistry</i> 48:8, 1305-1313 (2002)		
	2.	Mads N. Holten-Andersen et al., "Total Levels of Tissue Inhibitor of Metalloproteinases 1 in Plasma Yield High Diagnostic Sensitivity and Specificity in Patients with Colon Cancer", <i>Clinical Cancer Research</i> , Vol. 8, 156-164, January 2002		
	3.	Standard Search Report, in connection with application No. 32127 DK 01, 8 April 2002, Denmark (9 references)		
	4.	Zhou, et al., "Identifying Markers for Pancreatic Cancer by Gene Expression Analysis," <i>Cancer Epidemiology, Biomarkers & Prevention</i> , (1998), 7(2), 109-112.		
	5.	Wood, et al., "In Situ Hybridization Studies Of Metalloproteinases 2 And 9 And TIMP-1 And TIMP-2 Expression In Human Prostate Cancer," <i>Clinical & Experimental Metastasis</i> (1997), 15(3), 246-258.		
	6.	Jung, et al., "Quantification Of Matrix Metalloproteinases And Tissue Inhibitors Of Metalloproteinase In Prostatic Tissue: Analytical Aspects", <i>Prostate</i> , (1998), 34(2), 130-136, New York.		
	7.	Naruo, et al., "Serum Levels of a Tissue Inhibitor of Metalloproteinases-1 (TIMP-1) in Bladder Cancer Patients", <i>International Journal of Urology</i> , Churchill Livingstone, Tokyo, JP, vol. 1, no. 3, September 1994.		
	8.	Zucker, et al., "Plasma Assay of Gelatinase B: Tissue Inhibitor of Metalloproteinase Complexes in Cancer," <i>Cancer</i> , American Cancer Society, Philadelphia, PA, vol. 76, no. 9, August 15, 1995.		
	9.	Henriet, et al., "Tissue Inhibitors of Metalloproteinases (TIMP) in Invasion and Proliferation", <i>APMIS</i> , Copenhagen, DK, vol. 107, no. 1, 1999.		

FOREIGN PATENT DOCUMENTS

Examiner Initial	Cite No.	FOREIGN PATENT DOCUMENT		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	TRANSLATION	
		Country Code:	Number - Kind Code (if known)				YES	NO
SR ↓	10.	WO	00/62070 A	10-19-2000	Holten-Andersen et al.		<input type="checkbox"/>	<input type="checkbox"/>
	11.	WO	00/20860 A	04-13-2000	Calbiochem Novabiochem Corp.		<input type="checkbox"/>	<input type="checkbox"/>
	12.	WO	93/20447 A	10-14-1993	The Research Foundation of State University of New York		<input type="checkbox"/>	<input type="checkbox"/>

EXAMINER SIGNATURE

DATE CONSIDERED

5/21/05

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FORM PTO-1449 (Modified)			Attorney Docket No.: 019829000310		Application No.: 09/546,573	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Applicant: HOLTEN-ANDERSEN, Mads			
			Filing Date: April 10, 2000		Group: 1643	
Reference Designation			U.S. PATENT DOCUMENTS			Page 1
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
52 AA	5,324,634	06/28/94	Zucker	435	7.23	
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
AB						
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
52 AC	Baker et al., "Serum Metalloproteinases and their Inhibitors: Markers for Malignant Potential," <i>Br. J. Cancer</i> 70:506-512 (1994)					
AD	Birkedal-Hansen et al., "Matrix Metalloproteinases: A Review," <i>Critical Reviews in Oral Biology and Medicine</i> 4:197-250 (1993)					
AE	Clark et al., "Polyclonal and Monoclonal Antibodies Against Human Tissue Inhibitor of Metalloproteinases (TIMP) and the Design of an Enzyme-Linked Immunosorbent Assay to Measure TIMP," <i>Matrix</i> 11:76-85 (1991)					
AF	Cooksley et al., "Immunoassays for the Detection of Human Collagenase, Stromelysin, Tissue Inhibitor of Metalloproteinases (TIMP) and Enzyme-Inhibitor Complexes," <i>Matrix</i> 10:285-291 (1990)					
AG	Cooper et al., "Platelet-derived Collagenase Inhibitor: Characterization and Subcellular Localization," <i>Proc. Natl. Acad. Sci. USA</i> 82:2779-2783 (1985)					
AH	DeClerck et al., "Inhibition of Invasion and Metastasis in Cells Transfected with an Inhibitor of Metalloproteinases," <i>Cancer Research</i> 52:701-708 (1992)					
AI	Fujimoto et al., "A One-step Sandwich Enzyme Immunoassay for Tissue Inhibitor of Metalloproteinases-2 Using Monoclonal Antibodies," <i>Clinica Chimica Acta</i> 220:31-45 (1993)					
AJ	Goldberg et al., "Interaction of 92-kDa Type IV Collagenase with the Tissue Inhibitor of Metalloproteinases Prevents Dimerization, Complex Formation with Interstitial Collagenase, and Activation of the Proenzyme with Stromelysin," <i>The Journal of Biological Chemistry</i> 267:4583-4591 (1992)					
AK	Hembry et al., "Immunolocalization of Tissue Inhibitor of Metalloproteinases (TIMP) in Human Cells Characterization and Use of a Specific Antiserum," <i>J. Cell. Sci.</i> 73:105-119 (1985)					
AL	Holtén-Andersen et al., "Quantitation of TIMP-1 in Plasma of Healthy Blood Donors and Patients with Advanced Cancer," <i>British Journal of Cancer</i> 80:495-503 (1999)					
AM	Jung et al., "Matrix Metalloproteinases 1 and 3, Tissue Inhibitor of Metalloproteinase-1 and the Complex of Metalloproteinases-1/Tissue Inhibitor in Plasma of Patients with Prostate Cancer," <i>Int. J. Cancer (Pred. Oncol.)</i> 74:220-223 (1997)					
AN	Jung et al., "What kind of Specimen Should be Selected for Determining Tissue Inhibitor of Metalloproteinases-1 (TIMP-1) in Blood?" <i>Clinica Chimica Acta</i> 254:97-100 (1996)					
AO	Jung et al., "Role of Specimen Collection in Preanalytical Variation of Metalloproteinases and Their Inhibitors in Blood," <i>Clinical Chemistry</i> 42:2043-2045 (1996)					
AP	Keyszer et al., "Circulating Levels of Matrix Metalloproteinases MMP-3 and MMP-1, Tissue Inhibitor of Metalloproteinases 1 (TIMP-1), and MMP-1/TIMP-1 Complex in Rheumatic Disease. Correlation with Clinical Activity of Rheumatoid Arthritis versus Other Surrogate Markers," <i>The Journal of Rheumatology</i> 26:251-258 (1999)					
AQ	Kjeldsen et al., "Subcellular Localization and Release of Human Neutrophil Gelatinase, Confirming the Existence of Separate Gelatinase-containing Granules," <i>Biochem. J.</i> 287:603-610 (1992)					
AR	Khokha and Waterhouse, "The role of tissue inhibitor of metalloproteinase-1 in specific aspects of cancer progression and reproduction," <i>Journal of Neuro-Oncology</i> 18:123-127 (1994)					

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FORM PTO-1449 (Modified)		Attorney Docket No.: 019829000310	Application No.: 09/546,573
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: HOLTEN-ANDERSEN, Mads	
		Filing Date: April 10, 2000	Group: 1643
<u>SR</u> AS	Khokha et al., "Suppression of Invasion by Inducible Expression of Tissue Inhibitor of Metalloproteinase-1 (TIMP-1) in B16-F10 Melanoma Cells," <i>Journal of the National Cancer Institute</i> 84:1017-1021 (1992)		
AT	Khokha et al., "Up-regulation of TIMP-1 Expression in B16-F10 Melanoma Cells Suppresses their Metastatic Ability in Chick Embryo," <i>Clin. Exp. Metastasis</i> 10:365-370 (1992)		
AU	Kleiner et al., "Stability Analysis of Latent and Active 72-kDA Type IV Collagenase: The Role of Tissue Inhibitor of Metalloproteinases-2 (TIMP-2)," <i>Biochemistry</i> 32:1583-1592 (1993)		
AV	Kodama et al., "A Sandwich Enzyme Immunoassay for Collagenase Inhibitor Using Monoclonal Antibodies," <i>Matrix</i> 9:1-6 (1989)		
AW	Liotta et al., "Cancer Metastasis and Angiogenesis: An Imbalance of Positive and Negative Regulation," <i>Cell</i> 64:327-336 (1991)		
AX	MacDougall and Matrisian, "Contributions of Tumor and Stromal Matrix Metalloproteinases to Tumor Progression, Invasion and Metastasis," <i>Cancer and Metastasis Reviews</i> 14:351-362 (1995)		
AY	Matrisian, "The Matrix-Degrading Metalloproteinases," <i>BioEssays</i> 14:455-463 (1992)		
AZ	Mimori, "Clinical Significance of Tissue Inhibitor of Metalloproteinase Expression in Gastric Carcinoma," <i>British Journal of Cancer</i> 76:531-536 (1997)		
BA	Moll et al., "Tumor Promoter-stimulated M, 92,000 Gelatinase Secreted by Normal and Malignant Human Cells: Isolation and Characterization of the Enzyme from HT1080 Tumor Cells," <i>Cancer Research</i> 50:6162-6170 (1990)		
BB	Moutsiaakis et al., "Characterization of Metalloproteinases and Tissue Inhibitors of Metalloproteinases in Human Plasma," <i>Connective Tissue Research</i> 28:213-230 (1992)		
BC	Murphy et al., "The N-Terminal Domain of Tissue Inhibitor of Metalloproteinases Retains Metalloproteinase Inhibitor Activity," <i>Biochemistry</i> 30:8097-8102 (1991)		
BD	Stetler-Stevenson et al., "Matrix metalloproteinases and Tumor Invasion: from Correlation and Causality to the Clinic," <i>Seminars in Cancer Biology</i> 7:147-154 (1996)		
BE	Stetler-Stevenson et al., "Tissue Inhibitor of Metalloproteinases (TIMP-2) A New Member of the Metalloproteinase Inhibitor Family," <i>The Journal of Biological Chemistry</i> 264:17374-17378 (1989)		
BF	Stetler-Stevenson et al., "Extracellular matrix 6: Role of matrix metalloproteinases in tumor invasion and metastasis," <i>The FASEB Journal</i> 7:1434-1441 (1993)		
BG	Thorgeirsson et al., "Tumor invasion, proteolysis, and angiogenesis," <i>Journal of Neuro-Oncology</i> 18:89-103 (1994)		
BH	Welgus et al., "Human Skin Fibroblast Collagenase: Interaction with Substrate and Inhibitor," <i>Collagen Rel. Res.</i> 5:167-179 (1985)		
BI	Wilhelm et al., "SV40-transformed Human Lung Fibroblasts Secrete a 92-kDA Type IV Collagenase Which Is Identical to That Secreted by Normal Human Macrophages," <i>The Journal of Biological Chemistry</i> 264:17213-17221 (1989)		
<u>▼</u> BJ	Zucker et al., "Plasma Assay of Gelatinase B: Tissue Inhibitor of Metalloproteinase Complexes in Cancer," <i>Cancer</i> 76:700-708 (1995)		
EXAMINER <u>1</u> DATE CONSIDERED <u>5/21/05</u>			

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (REV. 7-80) PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 59866.000002		SERIAL NO.: 09/546,573							
LIST OF MATERIALS CITED BY APPLICANT (Use several sheets if necessary)				INVENTOR'S NAME: Mads N. HOLTEN-ANDERSEN et al.		EXAMINER: S. Rawlings							
				FILING DATE: April 10, 2000		GROUP: 1642							
PATENT DOCUMENTS													
*EXAMINER INITIAL		DOCUMENT NUMBER						FILING DATE	NAME	CLASS	SUBCLASS	FILING DATE	
SR	A	10/	1	1	7	0	3	0	04/08/02	M. Holton-Andersen et al.			
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		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
												YES NO	
OTHER MATERIALS (Including Author, Title, Date, Pertinent Pages, Etc.)													
SR	B	Tracy A. Plumpton et al.; Development of an enzyme-linked immunosorbent assay to measure total TIMP-1 (Free TIMP-1 and TIMP-1 in combination with matrix-metalloproteinases) and measurement of TIMP 1 and CRP in serum; Elsevier Science B.V.; pp. 137-154; 1995											
↓	C	Zeng, Z.S. et al.; Abstract #2038: High levels of tissue inhibitor of metalloproteinase-1 (TIMP-1) in colorectal cancer, as determined by enzyme-linked immunosorbent assay (ELISA), correlate with poor outcome; Proceedings of the American Association for Cancer Research, Vol. 39; p. 298; March 1998											
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